REMARKS

This application is a continuation of Application Serial No. 09/823,199, filed March 3, 2001 (the "Parent Application"), which is a continuation-in-part of Application Serial No. 09/118,269, filed July 17, 1998, now U.S. Patent 6,245,044. In the Parent Application, the claims had been rejected as being anticipated by U.S. Patent 6,083,207 to Heck ("Heck") in accord with 35 U.S.C.§102(e). Reconsideration of this rejection is requested in view of this Preliminary Amendment.

As an initial matter, applicant's attorney respectfully questions to what extent Heck is in fact an appropriate reference under 35 U.S.C.§102(e). The instant application claims the benefit, at least in part, to an application filed July 17, 1998 – before the filing of the Heck application. Even assuming Heck is an appropriate reference, the current claims are directed to an aspect of the invention that is believed patentable over Heck.

Aspects of the instant invention are related to an epidural needle that permits the caregiver to selectively control the movement of a spinal needle with respect to an epidural needle. Specifically, as set forth in the independent claims, the epidural needle includes an elongate tube attached to a hub. A hollow bore in the tube is aligned with an open passageway in the hub. The hub includes a cavity disposed between its proximal and distal ends. A resilient member is provided disposed in that cavity. A clamp is provided that can be moved from an open position, in which the resilient member is unaffected, and a clamp position, in which strain on the resilient member reduces the inner diameter of the opening through the resilient member. In use, the spinal needle can be displaced freely within the epidural needle when the clamp is in the open position. At the election of the caregiver, the clamp can be moved into the closed position, in which the spinal needle is fixed with respect to the epidural needle. The securement of the needles is achieved without having to attach a separate structure during use. Rather, the hub, resilient member and clamp are always in place, allowing the caregiver to effect locking by merely sliding the clamp and release the lock by sliding the clamp back.

In contrast, Heck is related to a partitioned hemostasis valve system that is designed to mount onto the proximal end of a splittable sheath. A housing 12 has a generally clothespin-shape. Valve sections 38, 40 are disposed in each half of the housing. A spring 78 urges housing to a closed condition. In use, a medical device, such as a pacemaker lead, is advanced through a splittable sheath, which is already disposed in a patient's vein. The hemostasis valve system is then attached around the handle of the splittable sheath and over the device or lead. A split gasket 112, 113 of the hemostasis valve system forms a tight seal around the handle, preventing blood leakage. The valve sections 38, 40 are placed together and act like a conventional hemostasis valve. After use, the hemostasis valve system can be opened by forcing the wings together, and thereby open the housing. The hemostasis valve system can then be reused or thrown away. This operation is described at col. 9, lines 10-52 of the '207 patent. It is noted that the system is designed to permit sliding of the medical device through the valve when closed.

Independent Claim 1

Looking specifically at claim 1, the elongate tube includes a distal end that has a sharpened tip suitable for penetrating a patient's tissue. The Examiner has stated that the splittable valve housing 12 of Heck corresponds to the tube of claim 1. Putting aside the issue of whether the squat housing depicted in Heck is an elongate tube, Heck does not provide a sharpened tip at the distal end of the splittable valve housing. Further, one would not be disposed to modify Heck to include a sharpened tip on the valve housing. Indeed, the partitioned hemostasis valve of Heck is intended to be employed on a splittable sheath after the sheath is already in place. Consequently, there is neither need for nor benefit from sharpening the housing of Heck.

Claim 1 also recites that the hub has an open passageway therethrough and is attached to the proximal end of the elongate tube. The Examiner states that the valve section 38 corresponds to the hub. The valve section does not include an open passageway therethrough. At most, a short opening extends

partly through the valve section (see, e.g., Fig. 6 of Heck). In any event, the valve section of Heck is disposed within the splittable valve housing – which the Examiner contends corresponds to the elongate tube. Consequently, the valve section is not attached to the proximal end of the elongate tube as set forth in claim 1.

Claim 1 further recites that the resilient member is permanently mounted within the hub. The Examiner contends that, in Heck, a catheter that is selectively inserted through the valve corresponds to this resilient member. It is noted that there is no description of the catheter such that one could deduce whether it is resilient or not. In any event, such a catheter is not permanently mounted within the hub. Indeed, it is the very purpose of Heck to allow selective insertion and removal of the catheter.

Claim 1 further recites that the clamp is selectively moveable from an open position (wherein the inner diameter of the resilient member is unaffected) to a clamp position (wherein the clamp causes a strain to at least a portion of the resilient member to reduce the inner diameter of the resilient member). The Examiner contends that wings 70, 71 and lip 56 correspond to the clamp. Further the Examiner has cited Col. 6, lines 36-53 of the Heck patent for the proposition the structure of Heck will cause such a strain. Applicant's attorney respectfully asserts that there is no teaching or suggestion in Heck (in the cited section or elsewhere) for this feature. In fact, such a feature would be undesirable in Heck. If a catheter were inserted through the Heck valve, compressing the catheter would result in reduced fluid flow. Consequently, one would hardly be disposed to modify Heck to achieve this feature.

Independent Claim 10

Claim 10 recites a sharpened distal tip on the elongate tube and that the hub is attached to the proximal end of the elongate tube, as discussed above. Claim 10 further recites a spinal needle, freely axially moveable within the hollow bore of the tube, that is fixed with respect to the epidural needle when the inner diameter of the resilient member is reduced. As discussed above, there is no teaching that the catheter references in Heck would deform as set forth in Claim 10. Further, there is no teaching or suggestion to include a needle within the resilient member. Again, the Examiner has contended that the catheter of Heck corresponds to the resilient member. The Examiner now contends that Heck's description of the insertion of a medical device through the valve anticipates inserting a spinal needle through the catheter. This proposition is simply not supported by Heck's general reference to the insertion of medical devices through the hemostasis valve. There is certainly no teaching in Heck to insert a catheter through the valve (to serve as a resilient member), and then to insert a medical device (let alone a spinal needle) through that catheter for selective securement to an epidural needle.

Independent Claim 19

Claim 19 recites a sharpened distal tip on the elongate tube, as discussed above. Claim 19 further recites that the resilient member fixedly secured within the cavity of the hub and restrained from axial displacement with respect to the hub. These features are simply not taught of suggested by Heck. The valve of Heck is specifically designed to permit sliding of the catheter or medical instrument (which the Examiner contends corresponds to the resilient member). One would not be disposed to modify Heck to achieve the invention as set forth in claim 19 because, *inter alia*, securing the catheter to the valve would destroy this functionality.

CONCLUSION

The independent claims 1, 10 and 19 are believed patentable in view of Heck. The remaining claims depend from these claims are thus also believed patentable over Heck Should any issues remain outstanding, the Examiner is invited to call the undersigned.

Respectfully submitted,

James J. Murtha
Reg. No. 35,769

Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880
201-847-7160
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